REMARKS

Examiner interview summary

Attorney of record participated in a telephonic Examiner interview on June 2, 2007 and proposed an amendment to the independent claims which recites that the bridging portions have no apertures. The Examiner stated that it appeared as if the prior art bridging portions had apertures but that he would need to review the document to see if other embodiments had other configurations before making a final determination. The Examiner agreed to review reasons for non-obviousness of the reduced dimension of the bridging portions. Applicant respectfully thanks Examiner Dawson for his time in conducting this interview and for this opportunity to submit an RCE for review.

Amendment Fully Supported by the Original Disclosure

The above amendments add no new matter to the application, and the specification fully supports these amendments. For example, Applicant submits that support exists in paragraphs [0003], [0011] to [0012], [0016] to [0018], [0044] to [0045] and [0049] of Applicant's specification for amending independent claims 1 and 19 to include the following language:

> such that the one or more first and second connecting members are sufficiently spaced-apart to facilitate fine adjustment of the first component relative to the second component for substantially parallel alignment of the edge of the first component with the edge of the second component during closure of the wound or incision.

Support exists in paragraph [0016] and Figs. 1 through 7b of Applicant's specification for amending independent claims 1 and 19 to include the following language:

> having no apertures therein and...

Rejection Under 35 USC 102(b)

Claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29, and 34 have been rejected under 35 USC 102(b) as being anticipated by US Patent No. 6,329,564 to Lebner ("Lebner '564"). Applicant respectfully traverses this rejection and asserts that Lebner '564 fails to anticipate every element of Applicant's independent claims, as currently amended.

Specifically, the Office Action states the following language on Page 2:

> As shown most clearly in Figure 3, Lebner explains that the connectors have cutouts (47, 49) that allow drainage of exudates and application of medication (column 6, lines 30-33). The cutouts form two "bridging portions" that have a smaller width than the "attached portions", and the thinner bridging portions span the laceration.

Applicant agrees that Lebner '564 teaches connectors having cutouts and respectfully disagrees that the two "thinner bridging portions" flanking the cutout anticipate Applicant's reduced-width bridging portions, which have therein no cutouts. Applicant's connecting members have bridging portions with widths less than the widths of their attached portions. This bridging portion width is measured from outer perimeter to outer perimeter. Paragraph [0016] of Applicant's Specification describes this dimension:

> [0016] Average width is determined by measuring from the outer perimeters of the bridging portions and the outer perimeters of the attached portions.

Fig. 1 and Fig. 3 of Lebner '564 clearly show that the width of the connectors is consistent along their lengths. Measuring between the outer perimeters of the "thinner bridging portions" of the connectors in Lebner '564 would produce the same result as measuring between the outer perimeters of the attached portions of that device. Lebner '564 thereby fails to teach a bridging portion having an average width measured from outer parameter to outer parameter that is less than the average width of an attached portion. Applicant's independent claims 1 and 19 as amended now recite this distinction of having no apertures therein, further distinguishing Applicant's claims from those of Lebner '564.

Additionally, because of their narrowed width, the bridging portions of Applicant's invention enable the connecting members to function differently than the connectors of the Lebner '564 device. Applicant's bridging portions enable more adjustability of the connecting members as compared with the connectors of Lebner '564. Applicant's Specification describes this function of the narrowed bridging portions:

> [0017] This difference in width in the bridging portion relative to the attached portion affords advantages over prior art devices in which the width of connecting

> members was substantially constant along their length. If the bridging area were narrowed in such a device, the net effect would be...an increase in the range of adjustment (narrowing the width of the connecting members in the bridging portion effectively increases the distance between adjacent bridging portions).

Lebner '564, in contrast, teaches connectors having widths that are substantially constant along their length. The cutouts in the Lebner '564 connectors fail to alter the width of those connectors at any point along their length as measured from outer parameter to outer parameter. Thus, it will be recognized that Lebner '564 fails to teach narrowed bridging portions that enable an increase in the range of adjustment.

Because Lebner '564 fails to disclose each and every recited feature of at least independent claim 1 and claim 19, as currently amended, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC 102(b). Therefore, the 102(b) rejection of independent claim 1 and claim 19 as currently amended, should be withdrawn. Further, Applicant submits that claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29, and 34 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29, and 34 under 35 U.S.C. 102 (b) and indicate that these claims are allowable.

Claims 1-3, 10, 11, 17, 19-21, 28, 29 and 35 have been rejected under 35 USC 102(b) as being anticipated by US Patent No. 5,263,970 to Preller ("Preller"). The Office Action states the following on Pages 2 and 3 language:

> Preller discloses a two-component (12, 14) device (10)...Regarding the limitation "*the average width of the bridging portions being less than the average width of the attached portions*": the connectors of Preller can be described as having attached and bridging portions. As clearly illustrated in Figure 1, each connectors comprises a "bridging portion" that has a smaller width than the "attached portion" (tab 28).

Applicant respectfully submits that Preller fails to teach a device having two separate and distinct components.

The Preller device is a unitary device. Applicant's use of two independently positioned components enables a user to precisely align distinct wound edges on either side of the wound or incision to be closed. These two components are separate and distinct from one another. Each component of Applicant's device is applied individually to either side of the wound or incision to be closed and the connecting members of Applicant's device allow for lateral adjustment of the first component relative to the second component. Prellar, however, teaches a single, unitary device that restricts lateral adjustment and thereby fails to enable any fine adjustment.

In addition to failing to teach separate and distinct first and second components, Preller fails to teach sufficient spacing between the connecting members so as to facilitate fine adjustment or lateral adjustability either during positioning of the second anchoring member or after the two anchoring members are positioned but prior to fixing their relationship by attaching connecting members to anchoring members. Preller instead teaches numerous closely-spaced limbs, clearly shown without spacing in Figs. 1 and 2. Column 2, lines 30 through 33 further describe this lack of spacing:

> Prior to use, the limbs 24.1 and 26.1 are interconnected along lines or zones of weakness 27 which can be ruptured to separate the limbs 24.1 and 26.1.

Not only are the connectors of Preller without sufficient spacing therebetween, but they are interconnected initially, which precludes any spacing whatsoever. Such a design of Preller, at best, highly restricts the ability to adjust the initially applied strips 10, 14 laterally during wound closure.

Applicant's use of a two-component device having connecting members with spaced-apart bridging portions solves this problem associated with the cited prior art. Applicant's independent claims 1 and 19 as amended now disclose this feature of sufficiently spaced connecting members allowing for fine adjustment of the first and second component. Support for this amendment exists in Applicant's Specification at least at paragraphs [0003], [0011] to [0012], [0016] to [0018], [0044] to [0045] and [0049].

Applicant's claimed invention thus enables very fine adjustment of the wound closure device applied to wounds having a non-uniform wound edge. This fine adjustment produces a

result of minimal scarring to the skin. In particular, by reducing the average width of the bridging portion of the connecting element relative to the attached portions, Applicant's present invention effectively maximizes the ability of a user to adjust the positioning of the first component relative to the second component, in a direction substantially parallel to the edges from which the connecting members extend. (Please see paragraphs [0012] to [0016] of Applicant's disclosure.)

Because Preller fails to disclose each and every recited feature of at least independent claim 1 and claim 19, as currently amended, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC 102(b). Therefore, the 102(b) rejection of independent claims 1 and 19 should be withdrawn.

Further, Applicant submits that claims 1-3, 10, 11, 17, 19-21, 28, 29 and 35 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 1-3, 10, 11, 17, 19-21, 28, 29 and 35 under 35 U.S.C. § 102 (b) and indicate that these claims are allowable.

Rejection Under 35 USC 103(a)

Claims 4, 6-8, 12-15, 18, 22, 24-26, 30-33, and 36 have been rejected under 35 USC 103a as being unpatentable over U.S. Patent No. 6,329,564 to Lebner (Lebner '564) in view of U.S. Patent No. 5,979,450 to Baker, et al ("Baker et al."). (Because Claims 4, 6-8, 12-15, and 18, and 22, 24-26, 30-33, and 36 are dependent upon independent Claims 1 and 19, respectively, this response will address the rejection as it pertains to Claims 1 and 19). More specifically, the Patent Office states:

> Lebner fails to include a wound edge bar or a code on the components to distinguish different parts from one another...Baker teaches that a thin fild with adhesive should include a reinforced bar so that wrinkles do not form in the film when applied ot the skin (column 8, lines 45-49).
>
> Lebner also fails to include a code in the form of indicia or distinguishing colors on the device, but Baker teaches that colors, patterns, or other distinguishing characteristics can be used to differentiate between parts of the device (column 10, lines 5-10).

Applicant respectfully submits that a prima facia case of obviousness has not been established as the applied references fail to teach each and every element of the claims. Applicant submits that neither Lebner '564 nor Baker et al. disclose or suggest the combination of features recited in the at least independent claim 1 and claim 19, as currently amended. Applicant also submits that no proper combination of these documents disclose or suggest the combination of features recited in at least the independent claims.

As discussed above, Lebner '564 lacks any disclosure or suggestion with regard to the bridging portions having no apertures therein and the average width of the bridging portions being less than the average width of the attached portions. Applicant has demonstrated that the device of Lebner '564 is different than Applicant's above-noted instant invention, and that Lebner '564 does not disclose or suggest the above-noted features of Applicant's claimed invention.

Baker et al. fails to cure this deficiency. With regard to Baker et al., Applicant acknowledges that Baker et al. teaches a surgical incise drape 10 having a film 12 that includes an upper surface 13 and lower surface 15 extending from a leading edge 31 of the flexible film 12 to a trailing edge 32 of the flexible film 12. See Figures 1-3 and Col. 5, lines 31-42. Baker et al., however, lacks any disclosure or suggestion with regard to the combination of features recited in independent claim 1 and claim 19, as currently amended. For example, Baker et al. fails to teach a two-component device having a first and second set of connecting members. This precludes Baker et al. from teaching a two component device having connecting members with no apertures therein and with bridging portions having average widths that are less than the average widths of the attached portions.

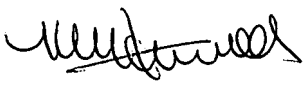
Applicant submits that no proper combination of Lebner '564 and Baker et al. discloses or suggests the combination of features recited in independent claim 1 and claim 19, as currently amended. Because the above-noted claims depend from the respective independent claim 1 and claim 19, as currently amended, Applicant further submits that no proper combination of Lebner '564 and Baker et al. discloses or suggests the combination of features recited in those dependent claims.

Accordingly, Applicant respectfully submits that the above-noted rejection under 35 USC 103(a) should be withdrawn.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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July 2, 2007
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